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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------|---------------|----------------------|--------------------------|------------------|
| 10/077,910 | 02/19/2002 | Patrick R. Connelly | BTI-9 3152 | |
| 37211 75 | 90 03/19/2004 | EXAMINER | | iner |
| BASCH & NICKERSON LLP | | | GETZOW, SCOTT M | |
| 1777 PENFIELD ROAD PENFIELD, NY 14526 | | | ART UNIT | PAPER NUMBER |
| , | | | 3762 | · R |
| | | | DATE MAIL ED: 03/19/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | Application No. | Applicant(s) | | | | |
| | 10/077,910 | CONNELLY, PATRICK | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Scott M. Getzow | 3762 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply sepecified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| Responsive to communication(s) filed on 2a) ☐ This action is FINAL. 2b) ☑ This 3) ☐ Since this application is in condition for allowar closed in accordance with the practice under E | action is non-final. nce except for formal matters, pro | | | | | |
| Disposition of Claims | | • | | | | |
| 4) ☐ Claim(s) 1-41 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-41 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or | | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the conference of the c | epted or b) objected to by the Edrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj | e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) | | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6.9. | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | | | | | |

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Claim Rejections - 35 USC § 112

1. Claims 31-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 31, line 10, 'second shielding' lacks antecedent basis.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

biocompatible layer as taught in paragraph 21.

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 3. Claims 1,3-6,8-11,13-16,18-21,23-26,28-31,33-35,37,38,40,41 are rejected under 35 U.S.C. 102(e) as being anticipated by Connelly et al (US 2002/0038135). Connelly teaches all of the subject matter of the above claims including primary and secondary modules 20,30, which can be encased in carbon or polymer shielding, as taught in paragraph 19, and which can also be encased in a

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Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 2,7,12,17,22,27,32,36,39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly et al in view of Mulier '142.

To use a metallic shielding, as taught by Mulier, would have been obvious in place of the types of shielding set forth in Connelly since such a shielding has been shown to be effective in preventing EMI from disrupting operation of the implanted pacemaker.

6. Claims 1,2,5,6,7,10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier '142.

Mulier teaches an implantable pacemaker which has a metallic shielding to protect internal circuitry from EMI. It is considered to be obvious to have the external layer of the housing of Mulier be biocompatible since such housing is implanted inside the patient. Implanted devices must be biocompatible otherwise adverse tissue reaction would occur. Further, control circuitry inside the housing is considered to be implicit; otherwise the pacemaker would not function.

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7. Claims 3,4,8,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier '142 in view of Luo et al.

The article to Luo teaches that carbon as well as polymer is good at shielding circuitry from EMI. To use such, in place of the metal shielding of Mulier, would have therefore been obvious as the skilled technician would be expected to experiment with the types of known shielding materials which best fit a specific application.

8. Claims 11,12,15,16,17,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier '142 in view of Nappholz et al '227.

Mulier teaches all of the subject matter of the above claims except a detection circuit that detects EMI. Nappholz teaches such a detection circuit in use in an implantable pacemaker. As taught in column 5, lines 6-11, when EMI is detected the pacemaker stops sensing and paces the heart at a predetermined rate.

Thus, Nappholz is capable of asynchronous (non-sensing) pacing when EMI is detected. It would have been obvious to use such a detection circuit with the device of Mulier in order to further increase the immunity of the pacemaker to EMI.

9. Claims 13,14,18,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier and Nappholz and further in view of Luo.

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It would have been obvious to use the carbon and polymer shielding of Luo with the device of Mulier and Nappholz for reasons mentioned supra.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott M. Getzow whose telephone number is (703) 308-2997. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott M. Getzow Primary Examiner Art Unit 3762

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